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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,298	04/07/2004	John Sefton	17224CON (AP)	7456

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EXAMINER	
BADIO, BARBARA P	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 09/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/820,298	SEFTON, JOHN	
	Examiner	Art Unit	
	Barbara P. Badio, Ph.D.	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-11 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-11 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 4/7/04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

First Office Action on the Merits

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 6-8, 10 and 11 of copending Application No. 09/367,712. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both encompass treatment of proliferative skin diseases by administration of tazarotene and a high potency corticosteroid. Unlike the copending application, the instant claims encompass a broader genus of corticosteroids. However, the instant claims recite corticosteroids such as mometasone furoate, betamethasone valerate and flucinonide (see claims 2, 5 and 10) and, thus, selection of a high-potency corticosteroid as recited by the copending application is prima facie obvious based on the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

3. Claims 4 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The language of the instant claims creates confusion because of the recitation of the phrase "a mid- or high-potency corticosteroid". The present specification discloses specific examples of compounds that are mid- or high-potency corticosteroid. However, apart from said examples, it is unclear which other corticosteroid(s) fall within said classification. The present specification also lacks definition/criteria that defines said corticosteroid(s) as either a mid- or high-potency corticosteroid. Thus, the skilled artisan in the art would be unable to determine the metes and bound of the claimed invention.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto ('906) and Nagpal et al. ('279) in combination.

Yamamoto teaches it is known in the art to use adrenocortical hormones, such as fluocinolone, fluocinolone acetonide, betamethasone valerate and clobetasol propionate, in the treatment of skin diseases such as psoriasis and atopic dermatitis (col. 1, line 11 – col. 2, line 55).

Nagpal et al. teaches it is known in the art to use tazarotene in the treatment of psoriasis (col. 1, lines 42-47).

The instant claims differ from the cited references by reciting the combined use of a corticosteroid and tazarotene in the treatment of skin diseases such as psoriasis. However, it is known in the art as indicated above to use each of the recited compound in the treatment of psoriasis. The combination of two compounds/compositions taught by the prior art to be useful for the same purpose to form a third composition that is to be used for the very same purpose would have been obvious to one having ordinary skill in the art at the time of the present invention. *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980). Thus, the claimed composition is prima facie obvious based on the combined teachings of the above references. The ordinary artisan in the art at the time of the present invention would have been motivated to use combination treatment for a number of reasons including the reduction of the adverse effect of each of the compound utilized.

Claims 3, 7 and 8 further differ from the reference by reciting specific pharmaceutical formulation containing 0.1% tazarotene.

However, the preparation of various formulations containing various amounts of the active ingredients for topical use is within the level of skill of one having ordinary skill in the pharmaceutical art and, thus, is within the level of skill of the ordinary artisan. In addition, finding the optimum amount of the active ingredient useful in the treatment of said disorder is also within the level of skill of the ordinary artisan and it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

6. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith ('074) or Sequeira et al. ('529) and Nagpal et al. ('279) in combination.

Each of Smith and Sequeira et al. teach the use of corticosteroids, such as betamethansone dipropionate and mometasone furoate in the treatment of psoriasis (see '074, col. 4, lines 47-67; '529, col. 1, lines 36-63).

Nagpal et al. teaches it is known in the art to use tazarotene in the treatment of psoriasis (col. 1, lines 42-47).

The instant claims differ from the cited references by reciting the combined use of a corticosteroid and tazarotene in the treatment of skin diseases such as psoriasis. However, it is known in the art as indicated above to use each of the recited compound in the treatment of psoriasis. The combination of two compounds/compositions taught by the prior art to be useful for the same purpose to form a third composition that is to be used for the very same purpose would have been obvious to one having ordinary

skill in the art at the time of the present invention. *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980). Thus, the claimed composition is prima facie obvious based on the combined teachings of the above references. The ordinary artisan in the art at the time of the present invention would have been motivated to use combination treatment for a number of reasons including the reduction of the adverse effect of each of the compound utilized.

Claims 3, 7 and 8 further differ from the reference by reciting specific pharmaceutical formulation containing 0.1% tazarotene.

However, the preparation of various formulations containing various amounts of the active ingredients for topical use is within the level of skill of one having ordinary skill in the pharmaceutical art and, thus, is within the level of skill of the ordinary artisan. In addition, finding the optimum amount of the active ingredient useful in the treatment of said disorder is also within the level of skill of the ordinary artisan and it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Other Matters

7. Applicant's remarks filed April 7, 2004 is noted. As indicated by applicant, the Board has decided that the data presented in the specification fails to show unexpected results in terms of efficacy of the claimed combination therapy.

For additional support, applicant refers to a reference by Gollnick (1990) and argues that the skilled artisan would expect that when two therapies are combined, the number of adverse events would be greater compared to the individual monotherapies. Thus, according to applicant a showing of reduction in the number of adverse events associated with the claimed combination is unexpected.

In response to said argument, the examiner notes that the incidence of treatment related adverse events for tazarotene plus mid- or high-potency corticosteroid as taught by Gollnick is almost identical, i.e., 32% and 31% respectively. Thus, Gollnick can not be seem as supporting applicant's assertion of unexpected results.

Lastly, the examiner disagrees with applicant's statement that the skilled artisan would expect the combination of two therapies to result in greater adverse events as compared to the individual monotherapies. One of the major reasons for combination therapy is reduction in adverse reaction of single therapy. Combination therapy results in the reduction in the amount of each of the drugs therein. Said reduction in the concentration of each of the active agent results in the reduction of the adverse effect seem with each and, thus, the skilled artisan in the art would have the reasonable expectation of a reduction in the number of adverse events with combination therapy versus the individual monotherapy. Said fact and the use of combination therapy are well known in the medical art.

Telephone Inquiry

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:00am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1616

BB
September 17, 2004